PAREXEL® ACCESS

INTEGRATED REAL-WORLD DATA SERVICES

A simplified solution to generate real-world insights
REAL-WORLD EVIDENCE HAS NEVER BEEN MORE IMPORTANT THAN IT IS TODAY

To ensure reimbursement and commercial success, Biopharmaceutical manufacturers must not only prove safety and efficacy, but also demonstrate the value of their product within its intended patient population and within the context of the current treatment environment. The most effective way for companies to advocate for reimbursement is to demonstrate that their product will have the expected value in a clearly targeted group of patients and eliminate risk for payers.

Increasingly, payers are demanding more real-world evidence of product value to support data-driven decision making, support the emergence of pay-per-performance schemes and address the sharp increase of products being developed under accelerated approval pathways.

To unlock the true potential of a promising new therapy, companies need to develop cost-effective and reliable access to real-world data to answer a broad array of clinical and commercial questions which supports late-stage product development, market access and the ongoing lifecycle management of a product.

While the demand for more evidence is growing, the amount of data available is growing right alongside it. The sheer volume and availability of real-world data has skyrocketed in recent years. Everything from wearables such as blood-glucose monitoring devices, to smartphone apps contributed to the rapid acceleration of how much real-world data is obtainable.
The need for real-world evidence is clear. Unfortunately, the pathway for companies to obtain the right data, data that presents actionable insights, is often unclear. The quality of existing real-world healthcare data can be poor and incomplete, since it is typically not collected for research purposes. A patient’s healthcare data is distributed across a diverse array of systems, which often results in gaps and can present significant challenges to connecting all the available data for a patient. To add to the challenge, there are many privacy regulations such as HIPAA, Safe Harbor etc. to navigate. Extensive talent from multiple functional disciplines are required to build a real-world data infrastructure, talent which may be difficult to recruit due to a shortage of experts in the field. Additionally, understanding exactly what data are needed by stakeholders, when certain types of data can be utilized and the significant regulatory uncertainty around use of real-world data, are only adding to the daily pressures.
MITIGATING CHALLENGES WITH A UNIQUE APPROACH

All of PAREXEL’s clients have unique needs pertaining to real-world evidence. Each use case requires a specific understanding of the clinical and commercial questions that the evidence must address. To better meet the needs of our clients, PAREXEL provides a tailored approach to each real-world evidence engagement – a customized strategy that is designed to help our client get fit-for-purpose data and the insights that they need - not just terabytes of data.

Our approach leverages the Connected Journey™, PAREXEL’s integrated range of solutions that provides a simplified way to access the insights that help our clients make critical decisions quickly, insights that are delivered as user-friendly visualizations that allow multiple stakeholders to engage more easily with the data. More importantly, the Connected Journey™ ensures that the right data is analyzed in the right way – and finds itself in the hands of the right people for smarter decisions.
For our Real-World Data Solutions, the Connected Journey™ has three core components:

1. A MULTIDISCIPLINARY APPROACH

   We bring together a multidisciplinary team of experts from technical, scientific, clinical and commercial disciplines including specialists in clinical research, medical affairs, HEOR, pricing and reimbursement, epidemiology, biomedical informatics, statistics and regulatory affairs. By bringing together a cross-functional team we are better placed to help our clients bridge the functional needs of their own stakeholders, enabling us to build a more robust real-world evidence strategy. A customized strategy that is built on deep understanding of current standard of care, the patient outcomes that are important to clinicians, payers and patients, and an understanding of the impact of emerging treatment or changes to the treatment guidelines for the specific patient population.

2. ROBUST PROCESSES TO DRIVE INSIGHTS

   PAREXEL have developed a robust framework that allows us to better determine the insights needed for the various stakeholders and the specific data requirements that underpins them. Our experts evaluate the market landscape to fully understand the dynamics of the current standard of care and patient profiling for the therapy. We work with our clients to understand the differentiation of a product and we look at the evidence that’s already available, either through clinical research, within the public domain or other healthcare data sources. We determine the evidence gaps and build a plan to fill those gaps to help drive insights to support decision-making and inform the value story. Since PAREXEL is often supporting the pivotal trials and late stage clinical development of our client’s product, we seek opportunities to earlier address the needs of commercial stakeholders in parallel with regulatory data requirements which offer greater efficiency to our clients. Additionally, we can leverage prospective research such as an observational study as a key tool in filling gaps that have been identified in the real-world data. We were pioneers in hybridized data source models, leveraging real-world data sources in clinical research – something that regulators have identified as a key evolution for industry.

3. PAREXEL ANALYTICS

   A seamless technology infrastructure is fundamental to our approach. As real-world data frequently needs to combine data from multiple technology architectures including data from healthcare sources, patient reported outcomes, electronic data capture (EDC) or a mobile health technology, a highly specialized infrastructure is needed. At PAREXEL, our Analytics Solutions consider logistics, distribution costs, tracking system updates, handling replacement devices and compliance. We provide seamless access to more than 300 secondary data sources and provide access to technology that can data-mine with patient-level linkage capability, provide analytics, data visualizations and support the creation of data lakes for structured and unstructured data.
PAREXEL understand that our clients don’t just want terabytes of real-world data – there are many providers who can offer such a service very well. Our clients come to PAREXEL because they want fit-for-purpose data and insights that will help them better address the needs of their regulatory, payer, physician and patient stakeholders. They want data validated for context and completeness, data that can support the analysis. They want a simplified, more efficient way of obtaining insights rather than subscribing to, or buying slices of, data from multiple providers, which in turn means investing heavily in an infrastructure to store and make sense of it. Clients rely on us to provide the technology infrastructure – a cloud-based store for their data which provides the capability to link large volumes of data that often sit in very different structures. They need us to provide the right analytics based on the type of data, the structure, the volume and the intended analysis. Finally, they rely on us to address gaps that may be present in existing real-world data sets by combining existing healthcare data with prospective research, leveraging our deep experience built through the conduct of over 600 peri/post-approval studies, and our broad expertise in clinical development, regulatory, market access, commercialization and product lifecycle management.
We are always available for a conversation.

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